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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,704

12/12/2005

Richard James Lewis

16095

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/537,704	<b>Applicant(s)</b> LEWIS ET AL.	
	<b>Examiner</b> MAURY AUDET	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☒ Newly proposed or amended claim(s) 15 and 16 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: 15 and 16.  
 Claim(s) objected to: 4 and 5.  
 Claim(s) rejected: 1-3, 6 and 7.  
 Claim(s) withdrawn from consideration: 11 and 17-21.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☒ Other: See continuation below.

/Maury Audet/  
 Examiner, Art Unit 1654  
 Full Sign. Auth. Program

Continuation of 4(e) Other:

I. First Ground: Applicant has changed the scope of the claims by amending Claim 4 to include to new species SEQ ID NO: 7 and 8, which were not pending at the time of the Final Rejection, or searched/examined as to being free of the art (even if the genus was, as Applicant has indicated; these nevertheless have to be individually searched/examined and determined allowable). Applicant asserts that SEQ ID NO: 7-8 were inadvertently deleted from the claims. Even if inadvertent, this changed the scope of the claims and the search/examination thereof. Which is clear on the record in the Final Rejection, where the Examiner accommodated Applicant's request for rejoinder of certain SEQ ID NOS; none of which were SEQ ID NOS: 7-8:

"Restriction Election and Traversal Acknowledged:

The FINAL restriction requirement is maintained as provided previously, as to the methods, BUT, the peptides have been rejoined. Specifically, Applicant's request for the rejoinder of the remaining, amended five (5) SEQ ID NOS: 5-6, 9, and 10-11, as well as the amended genus peptide formula of claim 1 is EXTENDED.

Claim 5, product, is hereby rejoined.

The method claims will be rejoined under In re Ochiai upon the Allowability of the product claims to which they depend.

Thereafter, upon allowability of any method claims formerly within a different group, the FINALITY of the restriction requirement as to these will be VACATED."

II. Second Grounds: SEQ ID NOS: 7-8 are amended into claim 4, which still has an outstanding Objection as depending from Obviousness Double Patenting Rejected base Claim 1 over SN '088's overlapping SEQ ID NO: 5; which Applicant acknowledges is now issued Patent US 7507717 B2. Thus making the Double Patenting Rejection no longer merely Provisional, since that application has Issued.

As Applicant indicated in his Summary of the Interview filed 11/19/09, 20 days after the After Final Amendment:

"The undersigned attorney also indicated to the Examiner that Applicants intended to file a terminal disclaimer to address the obviousness type double patenting rejection."

For reasons the Examiner is uncertain, Applicant has not filed this Terminal Disclaimer. Like the first ground above, SEQ ID NOS: 7-8 have not been searched/examined to determine if there are claimed species or obvious genus, that overlap in the now '717 B2 Patent, with SEQ ID NOS: 7-8.

Thus, the Double Patenting Rejection, the only rejection of record, remains outstanding (no longer just a provisional, per Applicant's notice the application has Issued).

[The 35 USC 112 2<sup>nd</sup> Rejection also remains outstanding since the Claim Amendments cannot be entered for the reasons stated. But it is noted the amendments made would overcome the 112 2<sup>nd</sup> rejection, at such time as these amendments become part of the record.].

III. Should Applicant not accept the allowance of claims 15-16 - per claimset filed 12/19/08, still of record - noted above (Allowed in Final Rejection), Applicant may wish to consider the filing of RCE in order to have all the amended claims considered, including those drawn to SEQ ID NOS: 7-8, and to file the Terminal Disclaimer.

IV. It is noted that the (Withdrawn) claims, drawn to Methods of Use, may be subject to 35 USC 112 1<sup>st</sup> Enablement issues, should Applicant seek rejoinder thereof under In re Ochiai, once the claims are amended to an Allowable Product.

V. Status of Other Claim Amendments:

Additionally, though Form-324 is not sent herewith, as definitively raising status-type amendmentst that are non-compliant; Applicant is asked to delete (not just line through) the subject matter of (Cancelled) claims 20-21 and identify Claim 22 as (Withdrawn-New), to put the amendments in proper form. See below.

1. Claims 11, 20-21 are (Cancelled) and must have the text deleted therefrom; like Applicant did in (Cancelled) claims 8-10 and 12-14.

See MPEP 714. C. Status Identifiers:

"A claim being canceled must be indicated as "canceled;" the text of the claim must not be presented. Providing an instruction to cancel is optional. Canceled and not entered claims must be listed by only the claim number and status identifier, without presenting the text of the claims."

2. Claim 22 is identified as (New). Claim 22 both depends from and depends to a Withdrawn claim. Thus, it is a (Withdrawn-New), and should be identified thereas,

See

i) MPEP 714 C. (E) Status Identifier (Withdrawn-New); &

ii) See MPEP 714 C. Status Identifiers (A):

"For any amendment being filed in response to a restriction or election of species requirement and any subsequent amendment, any claims which are non-elected must have the status identifier (withdrawn)."

[Specifically, Claim 22 depends from (Withdrawn-Currently Amended) Claim 18 and depends to (Withdrawn-Currently Amended) Claim 17.]